REMARKS

Claims 1-10 are pending in this action. Claims 1, 3-6, 8 and 10 remain in this application. Claims 1, 4, 5, 6, 8 have been amended by this amendment. Claims 2, 7 and 9 have been cancelled by this amendment.

Traverse Claim 4 Objection

The Examiner has objected to Claim 4 due to informality. Claim 4, line 2 comprises the term "expose" wherein the term should be the adjective "exposed". The Examiner is requesting appropriate correction.

The Applicant has amended Claim 4, Line 2. The word "exposed" is the correct adjective. The Applicant respectfully requests the objection to Claim 4 be withdrawn.

Traverse Rejection under 35 USC §102

The Examiner has rejected Claims 1, 3-6 as being anticipated by Winkler et al. (2000, Journal of Antimicrobial Chemotherapy, Vol. 26, pages 423-428). The Examiner states that Winkler et al. teach the use of vancomycin in water.

The Examiner further states that the intended use aspects of the claims were not considered as a limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

The Applicant disagrees with the Examiner's rejection of Claims 1, 3-6 based on the following: (1) Applicant's invention is a haemostatic paste; (2) Applicant's invention discloses 1:1 vancomycin to biocompatible carrier ration (weight to cubic centimeter volume); (3) Claims 3 and 4 depend ultimately on Claim 1 which the Applicant asserts is allowable, thus Claims 3 and 4 are also allowable; and (4) Claim 6 depends ultimately on Claim 5 which the Applicant asserts is allowable, thus Claim 6 is also allowable

(1) Applicant's invention is a haemostatic paste

The Examiner argues that Winkler et al. teaches the use of vancomycin in water. The Applicant argues that Winkler et al. teaches the use of vancomycin in water for bathing bone grafts to reduce infection.

In contrast, the Applicant respectfully argues that the present invention (amended Claims 1 and 5) teaches a haemostatic paste which is not aniticipated by Winkler et al. Applicant's invention is a paste-like admixture which is applied to cut bone surfaces or expose bone surfaces. The Applicant's invention has haemostatic/hemoocclusive capabilities when prepared in the specified ration. The Applicant respectfully argues that the product of the product claims of the instant invention is not taught by Winkler et al.

The Applicant respectfully asserts that the rejection of Claims 1 and 5 under 35 USC §102(a) should be withdrawn and allowance of Claim 1, as amended, and Claim 5, as amended, is respectfully requested. The Applicant argues that the product of the present invention is not taught by Winkler et al. and that the present invention is not patented or disclosed in a printed publication more than one year prior to the date of application

(2) Applicant's invention discloses 1:1 vancomycin to biocompatible carrier ration (weight to cubic centimeter volume)

The Examiner argues that Winkler et al. teaches the use of vancomycin in water. The Applicant argues that Winkler et al. teaches the use of vancomycin in water at a ration of 1 gram per 10 milliliters distilled water.

In contrast, the Applicant claims a 1:1 vancomycin to water (gram to cubic centimeter) ration (amended Claims 1 and 5). In the Applicant's preferred embodiment, 1 gram of powdered vancomycin is mixed with one cubic centimeter (milliliter) of biocompatible carrier. The Applicant respectfully asserts the 1:1 vancomycin to biocompatible carrier ration is not patented or described in Winkler et al.

The Applicant argues that the 1:1 ration of the present invention produces a paste (Original Specification Page 6, Lines 16-19). In constrast, the 1:10 ration of Winkler et al.

produces a solution (Winkler et al. Page 424, Column 2, 2nd paragraph). The Applicant further argues that the paste of present invention adheres to cut bone surfaces or exposed bone surfaces to provide haemostasis. The Applicant argues that the solution of Winkler et al. cannot provide adequate density to stop blood flow from a cut bone surface or exposed bone surface.

The Applicant respectfully asserts that the rejection of Claims 1 and 5 under 35 USC §102(a) be withdrawn, and allowance of Claim 1, as amended, and Claim 5, as amended, is respectfully requested. The Applicant argues that the present invention is not patented or disclosed in a printed publication more than one year prior to the date of application.

(3) Claims 3 and 4 depend ultimately on Claims 1 which the Applicant asserts is allowable, thus Claims 3 and 4 are also allowable

Regarding Claims 3 and 4, Claims 3 and 4 are dependent upon Claim 1. The Applicant has shown that Claim 1, as amended, is allowable. By their dependency on Claim 1, the Applicant submits that Claims 3 and 4 also define novel subject matter and allowance these claims is respectfully requested.

(4) Claim 6 depends ultimately on Claims 5 which the Applicant asserts is allowable, thus Claim 6 is also allowable

Regarding Claim 6, Claim 6 is dependent upon Claim 5. The Applicant has shown that Claim 5, as amended, is allowable. By its dependency on Claim 5, the Applicant submits that Claim 6 also defines novel subject matter and allowance this claim is respectfully requested.

The Applicant asserts that no new matter has been added to Claims 1, 5 and 8. The quantity of powdered vancomycin and the quantity of biochemical carrier in a ratio of 1 to 1, gram weight to cubic centimeter volume is disclosed in original Claims 2 and 7 and in the original specification (Page 6, Lines 16-23). The haemostasis property of the paste is disclosed in original Claims 4, 6 and 9 and in the original specification (Page 7, Lines 24-26).

The Applicant respectfully asserts that the rejection of Claims 1, 3-6 under 35 USC §102(a) be withdrawn, and allowance of the remaining Claims is respectfully requested. The

Applicant argues that the present invention is not patented or disclosed in a printed publication more than one year prior to the date of application.

Traverse Rejection under 35 USC §103

The Examiner rejected Claims 1-10 under 35 USC 103(b) as being unpatentable over Winkler in combination with Vogt et al. (US 2004/0052841 A1).

The Examiner states that Winkler et al teach the use of powdered vancomycin in water solution in bone graft studies. Winkler et al. teach vancomycin in water at 1 g/10 mL ration, however, Winkler et al. does not teach 1:1 vancomycin to water (weight to cubic centimeter volume). Winkler et al. teach the use for effects on bone repair and eradication of infection.

The Examiner states that Vogt et al. teach pharmaceutical compositions comprising vancomycin such as bone cements to treat bacterial infections in localized area in vivo. Vogt et al do not teach vancomycin in water or saline or Lactated Ringers.

The Examiner states the instant claims are to a composition comprising vancomycin with a biocompatible carrier, i.e., water, saline and Lactated Ringers. The Examiner states that the prior art teaches compositions comprising vancomycin with biocompatible carrier (Winkler et al. and Vogt et al. in combination). The Examiner further states that "the prior art teaches the use of such compositions for treatment of infections on the bone tissues of the body or for prevention of such infections due to insult to bony tissues (Winkler et al. and Vogt et al.). The prior art teaches the success of such techniques. Although the prior art does not teach a paste as claimed in your invention, the prior art teaches the application of the compositions to hard and soft tissues of the human and veterinary bodies as resorbable and non-resorbable implants."

The Examiner states that the prior use of vancomycin compositions for treatment of bony tissues for purposes of fighting infections while bony tissues repair or metallic or non-metallic implants are utilized. Even though Claims 2 and 7-10 are to a composition with a 1:1 vancomycin to carrier ration, from the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the Examiner states, "the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the

references, especially in the absence of evidence to the contrary, i.e., that a 1:1 ration had some unexpected result not obvious to one of skill in the art."

The Examiner notes that the intended use aspects of the claims were not considered as limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

The Applicant disagrees with the Examiner's rejection of Claims 1-10 based on the following: (1) Winkler et al. and Vogt et al. disclose the use of vancomycin solution as an antibiotic whereas Applicant's vancomycin paste invention is directed to haemostasis; (2) Applicant's invention does not require the vancomycin to be used in combination with resorbable or non-resorbable implants. Applicant's vancomycin haemostatic paste would have no role in the presence of bone graft or implants since these materials would not need haemostasis; (3) Applicant's invention has a spreadable consistency and adheres to a cut bone surface or exposed bone surface; (4) Applicant's invention does produce unexpected results not obvious to one of skill in the art; (5) Claims 3 and 4 depend ultimately on Claim 1 which the Applicant asserts is allowable, thus Claims 3 and 4 are also allowable; (6) Claim 6 depends ultimately on Claim 5 which the Applicant asserts is allowable, thus Claim 6 is also allowable; and (7) Claim 10 depends ultimately on Claim 8 which the Applicant asserts is allowable, thus Claim 10 is also allowable.

(1) Winkler et al. and Vogt et al. disclose the use of vancomycin paste as an antibiotic whereas Applicant's invention is directed to haemostasis

The Examiner argues that Winkler et al. and Vogt et al. teach the use of such compositions for treatment of infections on the bone tissues of the body or for prevention of such infections due to insult to bony tissues.

In contrast, the Applicant's invention is directed to a haemostatic paste for use on cut bone or exposed bone surfaces. The Applicant's invention is not directed to the use of implants for fighting infections. The Applicant argues that vancomycin mixed with a biocompatible carrier in a 1:1 ration produces a paste that adheres to a cut bone surface or exposed bone surface and provides haemostatic/hemoocclusive capabilities. The Applicant argues that neither Winkler et al. nor Vogt et al. disclose the use of vancomycin and biocompatible carrier as a haeomostatic

agent. The Applicant argues that the product of the present invention and those of Winkler et al. and Vogt et al. are different and that the present invention would not be obvious to one skilled in the art.

(2) Applicant's invention does not require the vancomycin to be used in bone grafts or with resorbable or non-resorbable implants. Applicant's vancomycin haemostatic paste would have no role in the presence of bone graft or implants since these materials would not need haemostasis.

The Applicant argues that Winkler et al. discloses the use of vancomycin inside bone grafts and Vogt et al. disclose the use of vancomycin in permanent or temporary implants in the form of tablets, molded bodies, fibers and granules. In fact, the Applicant's vancomycin haemostatic paste would have no role in the presence of bone graft or implants since these materials would not need haemostasis.

In contrast the Applicant's invention does not require the vancomycin to be used inside bone grafts or with resorbable or non-resorbable implants. The Applicant combines vancomycin powder with a biocompatible carrier in a specified gram to cubic centimeter volume ration to form a paste. The paste is applied directly to the cut bone surface or exposed bone surface. The paste forms a caramelized-like coating after prolonged contact with the cut bone or exposed bone surface. This caramelized-like coating results from the interaction between the vancomycin paste with blood and other body fluids (Original Specification, Page 9, Lines 7-11). "In clinical research and development studies, the present invention was used as the haemostatic agent in 500 patients undergoing sternotomy incisions. The vancomycin paste successfully occluded bleeding from the cut sternum during the surgical procedure in all 500 patients. Supplemental haemostatic agents were not required during the surgical procedure." (Original Specification, Page 10, Lines 16-20).

The Applicant respectfully asserts that the product of the present invention is not disclosed in Winkler et al. or in Vogt et al. and is not obvious to one skilled in the art.

(3) Applicant's invention has a spreadable consistency, adheres to a cut bone surface or exposed bone surface and provides haemostasis

The Applicant argues that Winkler et al. discloses vancomycin in water (1 gram/ 10 mL) to impregnate bone grafts. The ration disclosed in Winkler et al. results in a solution (Winkler et al. Page 424, Column 2, 2nd paragraph). In Vogt et al. the vancomycin is polymerized into a molded body (Page 1, Column 2, Paragraph 0012), used in self-curing calcium sulfate mixtures (Page 2, Column 1, Paragraph 0013) or used as part of resorbable and non-resorbable coatings, which are applied as metallic or non-metallic implants.

In contrast, the Applicant's invention is a paste that is applied directly to a cut bone surface or exposed bone surface. No impregnation of bone grafts or additional polymerization, calcium sulfate mixtures or implants are used in the present invention.

In the present invention, the thickness of the haemostatic paste composition is such that the composition is easily spread on the cut bone surface or exposed bone surface to stop bleeding. If the haemostatic paste composition contains an excessive amount of biocompatible carrier, the haemostatic paste will not adhere to the bone surface nor have the density to stop bleeding. If the haemostatic paste does not contain a sufficient amount of biocompatible carrier, the paste will contain excess powdered vancomycin which minimizes the ability of the paste to adhere to the bone surface (Original Specification Page 7, Line 24 to Page 8, Line 2).

The Applicant respectfully asserts that the product of the present invention is not disclosed in Winkler et al. or in Vogt et al. and is not obvious to one skilled in the art.

(4) Applicant's invention does produce unexpected results not obvious to one of skill in the art

The Examiner states that from the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

The Applicant argues that the use of vancomycin as a haemostatic paste as claimed in the present invention is an unexpected result and would not have been obvious to one skilled in the

art. Vancomycin is well known for its antibacterial properties and such properties are disclosed in Winkler et al. and Vogt et al. as well many other publications. However, neither Winkler et al. nor Vogt et al. disclose the use of vancomycin as a haemostasis.

The Applicant discloses the use of vancomycin as a haemostatic paste. "In clinical research and development studies, the present invention was used as the haemostatic agent in 500 patients undergoing sternotomy incisions. The vancomycin paste successfully occluded bleeding from the cut sternum during the surgical procedure in all 500 patients. Supplemental haemostatic agents were not required during the surgical procedure. In addition, only 1 patient developed infection of the site of the sternotomy incision. These studies also showed that the preparation of the vancomycin haemostatic paste was easily replicated and that the paste was easy to apply to the cut sternum." (original specification Page 10, Lines 16-24)

The Applicant has amended Claims 1 and 5 to include the haemostatis properties of the vancomycin paste. The Applicant respectfully asserts that the product of the present invention would not have been obvious to one skilled in the art at the time the invention was made.

The Applicant asserts that no new matter has been added to Claims 1, 5 and 8 The quantity of powdered vancomycin and the quantity of biochemical carrier in a ratio of 1 to 1, gram weight to cubic centimeter volume is disclosed in original Claims 2 and 7 and in the original specification (Page 6, Lines 16-23). The haemostasis property of the paste is disclosed in original Claims 4, 6 and 9 and in the original specification (Page 7, Lines 24-26).

(5) Claims 3 and 4 depend ultimately on Claim 1 which the Applicant asserts is allowable, thus Claim 3 and 4 are also allowable

Regarding Claims 3 and 4, Claims 3 and 4 are dependent on Claim 1. The Applicant has shown that Claim 1, as amended, is allowable. By their dependency on Claim 1, the Applicant submits that Claims 3 and 4 also define novel subject matter and allowance of these claims is respectfully requested.

(6) Claim 6 depends ultimately on Claim 5 which the Applicant asserts is allowable, thus Claim 6 is also allowable

Regarding Claim 6, Claim 6 is dependent upon Claim 5. The Applicant has shown that Claim 5, as amended, is allowable. By its dependency on Claim 5, the Applicant submits that Claim 6 also defines novel subject matter and allowance this claim is respectfully requested.

(7) Claim 10 depends ultimately on Claim 8 which the Applicant asserts is allowable, thus Claim 10 is also allowable

Regarding Claim 10, Claim 10 is dependent upon Claim 8. The Applicant has shown that Claim 8, as amended, is allowable. By its dependency on Claim 8, the Applicant submits that Claim 10 also defines novel subject matter and allowance this claim is respectfully requested.

The Applicant respectfully asserts that the rejection of Claims 1-10 under 35 USC §103(a) should be withdrawn and allowance of remaining Claims 1, 3-6, 8 and 10 is respectfully requested. The Applicant argues that the differences between the Applicant's invention and Winkler et al., in combination with Vogt et al. are such that the subject matter as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Traverse Rejection under 35 USC §112

The Examiner has rejected Claims 4, 6 and 9 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The claims are indefinite for the recitation of the phrase "capable of" wherein it is unclear as to whether the "capable of" characteristic is what the compounds of the claims is specifically used for.

The Applicant has amended Claims 4 and 6 to remove the phrase "capable of" and eliminate any confusion as to what the compound of the claims is specifically used for. Applicant has cancelled Claim 9 in this amendment.

The Applicant respectfully asserts that the rejection under 35 USC §112, second paragraph, should be withdrawn and allowance of Claims 4 and 6 is respectfully requested.

CONCLUSION

For the reasons set forth above, the Applicant submits that the claims all define novel subject matter. Applicant asserts that all claims submitted are proper, and respectfully requests the allowance of all remaining claims. Applicant respectfully requests that a timely Notice of Allowance be issued in this matter.

Very respectfully submitted,

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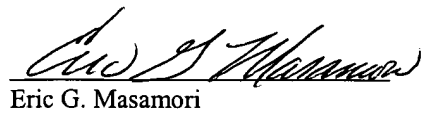

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